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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/484,577 | 01/18/00 | GORDON L | 07419-029001 |

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| EXAMINER | |
|---|---|
| ROARK, J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | 14 |

**DATE MAILED:** 09/20/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/484,577 | Applicant(s) GORDON ET AL. |
|---|---|---|
| | Examiner Jessica H. Roark | Art Unit 1644 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *5-8,15,17-27 and 30-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9-14,16,28,29 and 43* is/are rejected.

7)☐ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment, filed 6/25/01 (Paper No. 12), is acknowledged.
Claim 43 has been added.
Claims 1-4, 9-14, 16 and 28-29 have been amended.
*Claims* 1-43 *are pending.*

2. Applicant's election without traverse of Group II (SEQ ID NO:3) in Paper No. 12 is acknowledged.

Claims 5-8, 15, 17-27 and 30-42 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

*Claims* 1-4, 9-14, 16, 28-29 and 43 *are under consideration in the instant application.*

3. Sequence compliance: The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

4. Applicant's IDS, filed 7/30/01 (Paper No. 13), is acknowledged.

5. The Title of the invention is not descriptive. A new Title is required that is clearly indicative of the invention *to which the claims are directed.*

In addition, Applicant should avoid the use of *novel* in the Title, as patents are presumed to be novel and unobvious.

6. The Abstract of the invention is not descriptive. A new Abstract is required that is clearly indicative of the invention *to which the claims are directed.*

In addition, Applicant should avoid the use of *novel* in the Abstract, as patents are presumed to be novel and unobvious.

7. The formal drawings submitted 1/18/00 have been approved by the Draftsman.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

9. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

A hyperlink was found at least on page 22 at line 26. Applicant is requested to carefully review the specification for additional hyperlinks.

10. 35 U.S.C. § 101 reads as follows:

*"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".*

11. Claims 1-3, 9-14, 16, 28-29 and 43 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility.

While the art does not appear to recognize a sequence-specific or polypeptide-based diagnostic assay for giant cell arteritis (GCA), the specification discloses that a GST fusion protein comprising a polypeptide produced by nucleotides 1-369 of the genomic-derived nucleic acid sequence of SEQ ID NO:3 is differentially recognized by sera derived from patients with GCA versus sera derived from control individuals (e.g., discussion of SEQ ID NO:3 and the GST fusion construct on pages 29-30, and Figures 1 and 3). Thus an isolated or recombinant nucleic acid comprising this open reading frame subsequence from 1-369 of SEQ ID NO:3 (i.e., SEQ ID NO:3 itself, claim 4) appears to have a specific and substantial, credible utility.

However, the specification does not appear to teach whether SEQ ID NO:3 represents a full length coding sequence. The specification also does not appear to teach what structural aspects encoded by this particular nucleic acid are essential for the differential antibody recognition of the encoded polypeptide. Finally, the specification does not appear to teach a function of the encoded polypeptide, other than it can be differentially recognized by sera from GCA patients.

Because the specification does not appear to teach the structural basis for the differential antibody recognition of a polypeptide encoded by residues 1-369 of SEQ ID NO:3 (i.e., SEQ ID NO:4), it does not appear that the utility established for SEQ ID NO:3 can be extended to isolated nucleic or recombinant nucleic acids having 75, 85, or even 95% identity to SEQ ID NO:3; nucleic acids which hybridize to SEQ ID NO:3 (other than those comprising SEQ ID NO:3 itself), fragments of various lengths of hybridizing nucleic acids or nucleic acids having 75% identity to SEQ ID NO:3; expression vectors or transformed cells comprising nucleic acid variants of SEQ ID NO:3, or for methods of producing a polypeptide comprising a variant of SEQ ID NO:4. Also, an expression vector wherein the nucleic acid is operably linked in an antisense orientation does not appear to have a credible utility since the GCA sera would not be expected to bind a polypeptide encoded by the antisense strand, nor has a credible utility been established for any potential use of an antisense nucleic acid in therapy.

In addition, because the utility of SEQ ID NO:3 is based upon differential reactivity of serum antibody from GCA patients binding a polypeptide produced by expressing nucleotides 1-369 of SEQ ID NO:3 as a GST fusion protein; there does not appear to be a credible utility for a kit detecting the presence of nucleic acid sequences associated with GCA in a sample as set forth in claims 28 (by hybridization) or 29 (using an amplification primer pair). Even were detection of SEQ ID NO:3 by these methods shown to be useful in diagnosing GCA; the instant claims encompass variants of SEQ ID NO:3 (i.e., sequences with various levels of % identity or ability to hybridize) that do not have a specific and substantial, credible utility. Similarly, there does not appear to be a credible utility for a PCR primer pair that can amplify a variant of SEQ ID NO:3 or a subsequence thereof under *in situ* or *in vitro* conditions, even were PCR amplification of SEQ ID NO:3 itself shown to be diagnostic.

Thus, for the aforementioned reasons there does not appear to be either a specific and substantial, credible asserted utility or a well-established utility for the claimed.

Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

It is suggested that Applicant limit the claims to SEQ ID NO:3 and the 1-369 subfragment of SEQ ID NO:3 encoding SEQ ID NO:4 for which utility appears to have been established; and, if possible, provide evidence supporting the utility of nucleic acid-based detection approaches as diagnostic assays.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

13. Claims 1-3, 9-14, 16, 28-29 and 43 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In is further noted that, even were evidence provided that nucleic acid-based detection approaches have a credible utility as a GCA diagnostic assay; the skilled artisan still would consider it to be unpredictable as to which, if any, of the innumerable variants of SEQ ID NO:3 encompassed by the instant recitations of "nucleic acids with at least 75, 85, or 95 % identity to SEQ ID NO:3, or which hybridizes to SEQ ID NO:3"; would function in such a diagnostic assay. In addition, the conditions under which a primer pair would detect the presence of a nucleic acid sequence *in situ*, even were they specific for a nucleic acid sequence shown to have a diagnostic utility, are unpredictable.

Therefore, even were a diagnostic utility established for the detection of nucleic acid sequences associated with GCA, it would still be unpredictable as to which, if any, of the numerous variants of SEQ ID NO:3 would also function in those methods, or to establish a particular primer pair that would function in diagnostic assays, particularly *in situ* assays. Consequently, with respect to nucleic acid variants of SEQ ID NO:3 and particular primer pairs that function *in situ*, the experimentation left to those skilled in the art, would still be unnecessarily, and improperly, extensive and undue.

14. Claims 1-3, 9-14, 16, 28-29 and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The claims recite "nucleic acids with at least 75, 85, or 95 % identity to SEQ ID NO:3, or which hybridizes to SEQ ID NO:3" as part of the invention. However, there does not appear to be an adequate written description in the specification as-filed of the essential structural feature of a polypeptide encoded by the instantly recited nucleic acids. The genus of variant nucleic acids encompassed by "nucleic acids with at least 75, 85, or 95 % identity to SEQ ID NO:3, or which hybridizes to SEQ ID NO:3" is very large. In the instant case, although the specification discloses the nucleic acid sequence of SEQ ID NO:3, no function is provided for this open reading frame, other than that when expressed as a GST-fusion protein it is bound preferentially by antibodies from the sera of GCA patients. However, the structural property of SEQ ID NO:3 that provides this activity does not appear to be disclosed in the instant specification. Thus even were the claims limited to variant nucleic acids that encode a polypeptide specifically recognized by GCA patient antibodies; since there is no nexus between this function and a particular structure, such claims still would not provide an adequate written description of the genus of variant nucleic acids.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

15. SEQ ID NO:3 appears to be free of the art.

16. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
September 18, 2001

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
9/19/01